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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 09/727,855 12/01/2000 Tatsuo Hoshino 20516 4260 US/(C38435/111694) EXAMINER 7590 02/20/2004 NASHED, NASHAAT T **BRYAN CAVE LLP** 1290 AVENUE OF THE AMERICAS ART UNIT PAPER NUMBER 33RD FLOOR NEW YORK, NY 10104 1652

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/727,855	HOSHINO ET AL.
	Examiner	Art Unit
	Nashaat T. Nashed	1652
The MAILING DATE of this communica Period for Reply	tion appears on the cover sheet wi	th the correspondence address
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICA  - Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this communicable. If the period for reply specified above is less than thirty (30) does if NO period for reply is specified above, the maximum statute. Failure to reply within the set or extended period for reply will, Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).  Status	ATION.  FOR 1.136(a). In no event, however, may a recation.  ays, a reply within the statutory minimum of third orly period will apply and will expire SIX (6) MON, by statute, cause the application to become AE	eply be timely filed ry (30) days will be considered timely. ITHS from the mailing date of this communication. IANDONED (35 U.S.C. § 133).
1) Responsive to communication(s) filed of	on <u>01 December 2000</u> .	
2a) This action is <b>FINAL</b> . 2b)	☑ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-37 are subject to restriction and/or election requirement.		
Application Papers	una/or of collon requirement.	
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. §§ 119 and 120		
12) Acknowledgment is made of a claim fo a) All b) Some * c) None of:  1. Certified copies of the priority do 2. Certified copies of the priority do 3. Copies of the certified copies of the application from the International * See the attached detailed Office action for since a specific reference was included in 37 CFR 1.78.  a) The translation of the foreign languated acknowledgment is made of a claim for or reference was included in the first sentence.	cuments have been received. cuments have been received in A the priority documents have been I Bureau (PCT Rule 17.2(a)). or a list of the certified copies not domestic priority under 35 U.S.C. In the first sentence of the specific lage provisional application has be domestic priority under 35 U.S.C.	pplication No received in this National Stage received. § 119(e) (to a provisional application) ation or in an Application Data Sheet. een received. §§ 120 and/or 121 since a specific
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-3) Information Disclosure Statement(s) (PTO-1449) Pape	-948) 5) Notice of Ir	Summary (PTO-413) Paper No(s)  nformal Patent Application (PTO-152)  .

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Claims 1-37 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a process of making cartenoids, classified in class 435, subclass 67.
- II. Claims 8-26, 36 and 37, drawn to a DNA encoding mitochondrial suproxide dismutase, an organism comprising a disruption cassette for mitochondrial superoxide dismutase and said cassette, classified in class 435, subclass 320.1 and class 536, subclass 23.2..
- III. Claims 8-23, 27-29, 36 and 37, drawn to a DNA encoding cytoplasmic suproxide dismutase, an organism comprising a disruption cassette for cytoplasmic superoxide dismutase, and said cassette, classified in class 435, subclass 320.1 and class 536, subclass 23.2.
- IV. Claims 8-23, 30-32, 36 and 37, drawn to a DNA encoding catalase, an organism comprising a disruption cassette for catalase and said cassette, classified in class 435, subclass 320.1 and class 536, subclass 23.2..
- V. Claims 33 and 34, drawn to DNA encoding transit peptide, classified in class 536, subclass 23.1.
- VI. Claim 35, drawn to a method of locating objective protein, classified in class 435, subclass 4+.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I, and those of Groups II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cartenoids can be made by organic synthesis.

Inventions of Group I, and those of Groups V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the method of making cartenoids of Group I does not utilize the DNA of Group V, and it is an independent method of the method of Group VI.

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Inventions of Groups II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are independent chemical entities having different structure.

Inventions of Group II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, nucleic acid of Group II can be used to make the superoxide dismutase.

Inventions of Groups III-V, and that of Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the method of Group VI does not utilize any of the nucleic acid of Groups III-V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The invention of Group I contains claims directed to the following patentably distinct species of the claimed invention: SEQ ID NO's: 1-4, 6 and 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Gonzalo Marino on November 24, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nashaat T. Nashed Primary Examiner Art Unit 1652